SEP 0 8 2004

Attorney Docket No.: VASC 1000-12 US

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being Faxed to the United States Patent and Trademark Office

at 762,872<u>-9308 o</u>n 08 September 2004. Rule Jan

Paula Faulk Hurley

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventors:

Menno Kalmann

SC/Serial No.: 09/691,817 Confirm. No.: 5259

Filed: Title:

October 18, 2000

METHOD THEREFOR

ASSEMBLY FOR TREATING BLOOD VESSELS AND A

Art Unit: 3738

Customer No. 22470

PATENT APPLICATION

Examiner: David J. Isabella

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

It is requested that the information identified in this statement be considered by the Examiner and made of record in the above-identified application. This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56.

Since this is a continuation, divisional or continuation-in-part application, it is understood that the Examiner will consider all information which was considered by the Office in a parent application. MPEP 609.

Enclosed with this statement is a Form PTO/SB/08A. The Examiner is requested to initial the form and return it to the undersigned in accordance with M.P.E.P. 609.

Also enclosed with this statement is a copy of each cited document as required by 37 C.F.R. 1.98. However, since this application was filed after June 30, 2003, copies of U.S. Patents and U. S. Patent Application Publications are not enclosed. (See O. G. Notice of August 5, 2003.) The two U.S. patents cited herein correspond to References 2 and 4 of the Japanese office action.

For foreign language documents cited in a search report by a foreign patent office, the requirement for a concise explanation of relevance is satisfied by the submission herewith of an English language version of the search report from the Japanese Patent Office mailed June 8, 2004. MPEP 609A(3).

If a written English-language translation of a non-English language document, or portion

thereof, is within the possession, custody or control of, or is readily available to any individual designated in 1.56(c), a copy of the translation accompanies this statement, 37 C.F.R. 1.98(a)(3)(ii), and satisfies the requirement for a concise explanation of relevance, MPEP 609A(3). Attached to Reference B1 (JP 04218154) is a translation regarding the description of the drawings. Attached to Reference B2 (JP 61-220648) is a translation for parts and elements indicated by the numerals in the drawings.

This statement should be considered under 37 C.F.R. 1.97(c) because it is being filed before the mailing date of a FINAL office action, a Notice of Allowance, or an action that otherwise closes prosecution in the subject application, whichever occurs first, AND one of the following statements as set forth in 37 C.F.R. 1.97(e) applies:

- (1) That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- (2) That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry. no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Fee Authorization. The Commissioner is hereby authorized to charge underpayment of any additional fees or credit any overpayment associated with this communication to Deposit Account No. 50-0869 (VASC 1000-12). A duplicate copy of this authorization is enclosed.

> Respectfully submitted, Haynes Beffel & Wolfeld LLP

Date: 08 September 2004

James F. Hann Haynes Beffel & Wolfeld LLP P.O. Box 366; 751 Kelly Street Half Moon Bay, CA 94019 Ph. (650) 712-0340 Fax (650) 712-0263 jhann@hmbay.com

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PTC/SB/08A (08-00)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

| Complete If Known | | | | |
|------------------------|-------------------|--|--|--|
| Application Number | 09/691,817 | | | |
| Filing Date | October 18, 2000 | | | |
| First Named Inventor | Menno Kahlmann | | | |
| Group Art Unit | 3738 | | | |
| Examiner Name | David J. Isabella | | | |
| Attorney Docket Number | VASC 1000-12 | | | |

| | | | U.S. PATENT DOC | UMENTS | |
|----------------------|------|------------------------------|-------------------------------|--|--|
| Examiner Initials | No.1 | U.S. Patent Documer Kind Co | Name of Patentee or Applicant | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear |
| | A1 | 5,316,023 | Palmaz et al. | 05-31-1994 | Figures Adsgar |
| | A2 | 5,662,713 | Andersen at al. | 09-02-1997 | - |
| | A3 | | | 111 111 | |
| | A4 | | | | |
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| Exeminer Initiale* | Cite No.1 | Foreign Patent Document | | | | Date of Rublication of | Pages, Calumns, Lines. | T |
| | | Office3 | Number | Kind Code ^s (<i>if known</i>) | Name of Patentes or Applicant of Cited Document | Cited Document MM-DD-YYYY | Where Relevant Passages or Relevant Figures Appear | 78 |
| | <u>B1</u> | JР | 04218154 | Α | Yoshida Hideaki | 08-07-1992 | | 1 |
| | _B2 | JР | 61-220648 | A | Inoue Kanji | 09-30-1986 | | + |
| | B3 | | | | | - | | +- |
| | B4 | | | | ~ | | | + |
| | B5 | | | | *** | · · · · · · · · · | | |
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| Examiner | Date | |
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| Planeture | | |
| Signature | Considered | |
| | | |

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Occuments. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. ⁶ Applicant is to place a check mark haze if English language Translation is attached.



Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Tims will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Mailing No.: 196244 Mailed: June 8, 2004

TRANSLATION OF THE OFFICIAL ACTION

Patent application No. 511645/1996 May 26, 2004 Drafted: Hiroaki HIRAI Examiner:

Attorney(s): Hisao OKUYAMA, and three others Applied provision(s): Section 29 (2) of Patent Law

This application is deemed to be rejected for the following reasons. If any argument is to be presented, please submit a Statement of Argument within three months from the date of mailing. (Translator's note: Headings in square brackets are added for ease of understanding.)

REASONS

[LACK OF INVENTIVE STEP] The present invention of this application claimed in the claim(s) pointed out below is unpatentable under the provision of Section 29 (2) of Patent Law, since this invention could have been easily thought of by anyone who had general knowledge in this art field based on the invention described in the publication(s) listed below which was/were distributed in Japan or in a foreign country before the filing date.

REMARKS

Claims 1, 2 and 4-6References 1 and 2

Reference 1 describes an artificial blood vessel comprising "a shape memory alloy of U-shaped type (b)" (corresponding to "diameter arranging means" of the present invention, referring to Fig. 1(b) of reference 1), "a catheter" (corresponding to "introducing means"), and "artificial blood vessel inserting part sheath" (corresponding to "sheath-like protective cover"). The transformation temperature of the shape memory alloy is described to be set slightly lower than body heat (refer to claims).

Reference 2 describes "a nose piece (772)" corresponding to "blood vessel widening means" and "bunging means" (refer to page 28, line 16).

Therefore, it would not have been very difficult to

arrange the structure described in claims 1, 2 and 4-6 by combining References 1 and 2.

Claim 3
References 1-3

Reference 3 describes diameter arranging means having a "ring cover (4)" corresponding to "expandable gauze". Therefore, it would not have been very difficult to arrange the structure described as claim 3 by applying this component to the artificial blood vessel described in Reference 1.

Claims 7 and 8 References 1-4

Reference 4 describes a structure having a "balloon (183A, 183B)" corresponding to "pressure exerting means".

List of References Cited

1. JP 4-218154 A

2. JP 8-502428 T

3. JP 61-220648 A

4. JP 5-344989 A

Record of the Prior Art Search

Searched field(s): IPC 7th edition, A61N 2/06

A61M 29/00

Document(s): JP 5-317344 A

JP 6-23031 A JP 5-269197 A JP 63-214264 A

This record has not been relied on in the reject of the present application.

Comments by Okuvama & Co.

9-173

In this Office Action the Examiner rejected all pending claims (claims 1-8 based on your letter of September 4, 2002) for lack of inventive step over the following four references.

Reference 1 (JP 4-218154 A) has no patent family. We are attaching a copy of the English abstract from JPO. In addition, our translation regarding the description of drawings is as follows:

Figs. 1(a) and 1(b) are perspective views of preferred embodiments of an artificial blood vessel according to the present invention with a shape memory alloy of a spiral type (s) or a U-shaped type (b);

Fig. 2 is a sectional view of the artificial blood vessel shown in Fig. 1(a), wherein the shape memory alloy (s) is incorporated into a polyurethane material of tube (p);

Fig. 3(a) shows a delivery catheter enable to load the contracted artificial blood vessel therein for introducing the artificial blood vessel into a blood vessel;

Figs. 3(b) and 3(b') show a catching catheter enable to grasp the artificial blood vessel, Fig. 3(b) being an enlarged view of a grasping part of it, Fig. 3(b') being an enlarged view of a controlling handle part of it;

Fig. 3(c) shows a folded pulling wire inserted into a guiding catheter;

Fig. 4 shows a method for introducing and placing the artificial blood vessel at a prescribed position of a blood vessel;

Fig. 4-1 shows that the catching catheter (G) inserted from one side of a blood vessel grasps the folded pulling wire (W) inserted from the other side of it:

Fig. 4-2 shows that the grasping part of the catching catheter (G) is pulled out of the other side of the blood vessel by pulling the pulling wire (W) back:

Fig. 4-3 shows that the artificial blood vessel (SAP) loaded in the delivery catheter (T) is introduced in the blood vessel by pulling the catching catheter (G) back; and

Fig. 4-4 shows that the artificial blood vessel (SAP) kept to be grasped with the catching catheter (G) is expanded and placed at a prescribed position of the blood vessel by pushing the artificial blood vessel by a pushing rod.

Reference 2 (JP 8-502428 T) corresponds to international publication No. WO 94/12136 published on June 9, 1994. We are attaching a copy of the front page of this international publication.

Reference 3 (JP 61-220648 A) does not have any commercially available English abstracts. Our translations for parts and elements indicated by the numerals shown in the drawings is as follows:

- (1) artificial blood vessel,
- (2) main body made from polyester fiber or polytetrafluoroethylene,
 - (3) anchoring ring made from a shape-memory allow,
- (4) ring cover made from the same material as main body,
 - (5) groove for ease in anchoring,
 - (6) natural blood vessel, and
 - (7) cut line for transformation of ring.

Reference 4 (JP 5-344989 A) corresponds to U.S. Pat. No. 5,316,023. We are attaching a copy of the front page of this U.S. patent document.

We look forward to receiving your instructions as to how we may respond to the outstanding Action. If you have any questions or need more information, please do not hesitate to let us know.